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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/583,953	05/10/2007	Guenter Bellmann	P04167	1499
23702 7590 04/02/2009 Bausch & Lomb Incorporated One Bausch & Lomb Place Rochester, NY 14604-2701				
EXAMINER				
CHOI, FRANK I				
ART UNIT		PAPER NUMBER		
1616				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/583,953

Applicant(s)

BELLMANN ET AL.

Examiner

FRANK I. CHOI

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SF 298)
Paper No(s)/Mail Date 5/10/2007
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____

DETAILED ACTION

Claim Rejections - 35 USC § 101/112

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-9, 12-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2-6 set forth broad ranges followed by narrower ranges as evidenced by the use of the term "preferably". A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949).

Claims 5, 7, 8 recite a group, however, the group is open-ended, i.e. the scope of the group is indefinite. A Markush group by definition is a closed set of members, as such, the set cannot be open-ended.

Claims 12, 13 provides for the use of product and claim 14 provides for a means for a supplementary balanced diet or means for a supplementary, but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 12-14 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(c) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Claims 1-7,9 are rejected under 35 U.S.C. 102(b or e) as being anticipated by Rosenberg et al. (US Pat. 6,579,544).

Rosenberg et al. expressly discloses a dietary composition containing zeaxanthin, lutein, zinc, copper, vitamin C and vitamin E falling within the scope of the claimed invention:

EXAMPLE

The following formulae represent specific embodiments of the invention. These embodiments can be prepared by blending together the stated dry raw materials in an agglomerator to result in a product having a uniform composition with the precise proportions of the components as indicated. More than one ingredient is oil-based, and such ingredients are preferably blended and distributed over the dry ingredients. If flax seed oil is to be added, said oil is mixed with the blended dry ingredients and oil-based ingredients, and the resulting mixture is a product having a uniform composition. The agglomerated material is then preferably placed in capsules according to methods well known in the art, such as is summarized in Remington's Pharmaceutical Sciences, in quantities of one ration per capsule. As a frame of reference, Formulation II, as set out below, is intended to be encapsulated in 7 "00" capsules, each containing about 1.0 to 1.3 g/ml. Other formulations can be encapsulated in any suitable number and size of capsules, in accordance with the knowledge of one of ordinary skill in the relevant art of capsule sizing and quantifying. Size "00" capsules have a capsule volume of about 0.95 ml. Other capsule sizes could be selected according to principles well known in the pharmaceutical arts. In the preferred embodiment, the composition comprises the following ingredients stated in amounts by weight or international units (IU):

Ingredients	Formulation Numbers							
	I	II	III	IV	V	VI	VII	VIII
Vitamin A (IU)	2000	10,000		8000		5000		
Vitamin D (IU)	125	400		500		600		
Vitamin E (IU)	250	400	600	300	550	700	400	500
Vitamin K (µg)	300	80		20		50		
Vitamin C (mg)	500	1500	1000	1000	1500	750	1200	600
Thiamine (mg)	50	10			5	1		
Riboflavin (mg)	50	10			5	1		
Niacin (mg)	50	40			10	20		
Pyridoxine (mg)	1	10			40	30		
Folate (µg)	100	600			900	120		

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-continued

Ingredients	Formulation Number							
	I	II	III	IV	V	VI	VII	VIII ⁵
Vitamin	5	25			50	30		
B-12 (µg)					800	500		
Biotin (µg)	100	400			5	30		
Pantothenic	100	20						
Acid (mg)								10
Ca (mg)	1500	1000	800	500	1200	1000	1300	800
Mg (mg)	100	400		500		800		
Cr (µg)	300	150				10		200
Cu (mg)	1	3				5		1
I (µg)	10	150				300		50
Fe (mg)	2	5				10		5
Mn (mg)	50	10				1		30
Mo (µg)	200	75				10		100
Se (µg)	20	200				500		100
Zn (mg)	5	20				100		50
B (mg)	2	1				5		0.5
V (µg)	20	10				1		50
α-Carotene	400	196		20				200
(µg)								
β-Carotene	1	6		8			10	
(mg)								
Crypti-	100	49	20		90			
oxanthin								
(mg)								25
Lutein (mg)	5	10		20	10	15		
Lycopene	1	2		10	5			
(mg)								
Zeaxanthin	800	539		200				600
(µg)								
Citrus	150	50					10	100
Bio-								30
flavonoids								
(mg)								
Grape Seed	5	25					100	50
Extract (mg)								
Quercetin	100	25					100	50
(mg)								35
Rutin (mg)	5	25					100	75
Soybean	100	62					250	10
isoflavones								
(mg)								
Flax Seed	1000	500				100		2000
Oil (mg)								40
Glucoamine	500	750				1000		200
(mg)								
Chondroitin	1000	600				150		1200
(mg)								
α-Lipoic	25	50			100		5	
Acid (mg)								45
Coenzyme	25	10					5	50
Q10 (mg)								

(Columns 22, 23).

Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenberg et al. (US Pat. 6,579,544).

Rosenberg et al. is being cited herein for the same reasons as above. Further, it is disclosed that various compounds can be added that are useful in the manufacture of nutritional supplements, including lactose, dyes, etc. and that tablets can be prepared (Column 25).

Rosenberg et al. discloses nutritional supplements containing zeaxanthin, lutein, zinc, copper, vitamin C and vitamin E. The difference between Rosenberg et al. and the claimed invention is that Rosenberg et al. does not expressly disclose adding a coating substance or the specific amounts in claims 10 and 11. However, the prior art amply suggests the same as the prior art discloses that dyes can be added and that the composition is suitable for nutritional supplementation. As such, it would have been well within the skill of one of ordinary skill in the art would have been motivated to add a dye to distinguish the product visually and would have been motivated to use various amounts of the claimed active agents in order to meet the varying needs of the person or persons taking the nutritional supplement.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Conclusion

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a compressed schedule and may be reached Monday, Tuesday, Wednesday and Thursday, 6:00 am – 4:30 pm (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Johann R. Richter, can be reached at (571)272-0646. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications

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may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frank Choi
Patent Examiner
Technology Center 1600
April 2, 2009

/Johann R. Richter/

Supervisory Patent Examiner, Art Unit 1616